Senate File 2312 - Introduced

SENATE FILE 2312
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO SSB 3074)

A BILL FOR

An Act relating to the electronic prescribing of prescription drugs including controlled substances, making penalties applicable, and providing penalties.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.308, Code 2018, is amended by striking the section and inserting in lieu thereof the following:

124.308 Prescriptions.

1. Except when dispensed directly by a practitioner to an ultimate user, a prescription drug as defined in section 155A.3 that is a controlled substance shall not be dispensed without a prescription, unless such prescription is authorized by a practitioner and complies with this section, section 155A.27, applicable federal law and regulation, and rules of the board.

2. *a.* Beginning January 1, 2020, every prescription issued for a controlled substance shall be transmitted electronically as an electronic prescription pursuant to the requirements in subsection 2, paragraph *"b"*, unless exempt under subsection 2, paragraph *"c"*.

b. Except for prescriptions identified in paragraph *"c"*, a prescription that is transmitted pursuant to paragraph *"a"* shall be transmitted to a pharmacy by a practitioner or the practitioner's authorized agent in compliance with federal law and regulation for electronic prescriptions of controlled substances. The practitioner's electronic prescription system and the receiving pharmacy's dispensing system shall comply with federal law and regulation for electronic prescriptions of controlled substances.

c. Paragraph *"b"* shall not apply to any of the following:

(1) A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

(2) A prescription authorized by a licensed veterinarian.

(3) A prescription dispensed by a department of veterans affairs pharmacy.

(4) A prescription requiring information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.

(5) A prescription for a compounded preparation containing two or more components.

(6) A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.

(7) A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.

(8) A prescription issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location, provided that a prescription issued pursuant to this subparagraph shall indicate on the prescription that the practitioner or pharmacy is experiencing a temporary technical or electronic failure.

(9) A prescription issued in an emergency situation pursuant to federal law and regulation rules of the board.

d. A practitioner, as defined in section 124.101, subsection 27, paragraph *"a"*, who violates paragraph *"a"* is subject to an administrative penalty of two hundred fifty dollars per violation, up to a maximum of five thousand dollars per calendar year. The assessment of an administrative penalty pursuant to this paragraph by the appropriate licensing board of the practitioner alleged to have violated paragraph *"a"* shall not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of an administrative penalty pursuant to this paragraph, which shall initiate a contested case proceeding under chapter 17A. A penalty collected pursuant to this paragraph shall be deposited into the drug information program fund established pursuant to section 124.557. The board shall be notified of any administrative penalties assessed by the appropriate professional licensing board and deposited into the drug information program fund under this paragraph.

e. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception under paragraph *"c"* and may dispense a prescription drug pursuant to an otherwise

valid written, oral, or facsimile prescription. However, a pharmacist shall exercise professional judgment in identifying and reporting suspected violations of this section to the board or the appropriate professional licensing board of the practitioner.

3. A prescription issued prior to January 1, 2020, or a prescription that is exempt from the electronic prescription requirement in subsection 2, paragraph "*c*", may be transmitted by a practitioner or the practitioner's authorized agent to a pharmacy in any of the following ways:

a. Electronically, if transmitted in accordance with the requirements for electronic prescriptions pursuant to subsection 2.

b. By facsimile for a schedule III, IV, or V controlled substance, or for a schedule II controlled substance only pursuant to federal law and regulation and rules of the board.

c. Orally for a schedule III, IV, or V controlled substance, or for a schedule II controlled substance only in an emergency situation pursuant to federal regulation and rules of the board.

d. By providing an original signed prescription to a patient or a patient's authorized representative.

4. If permitted by federal law and in accordance with federal requirements, an electronic or facsimile prescription shall serve as the original signed prescription and the practitioner shall not provide a patient, a patient's authorized representative, or the dispensing pharmacy with a signed, written prescription. An original signed prescription shall be retained for a minimum of two years from the date of the latest dispensing or refill of the prescription.

5. A prescription for a schedule II controlled substance shall not be filled more than six months after the date of issuance. A prescription for a schedule II controlled substance shall not be refilled.

6. A prescription for a schedule III, IV, or V controlled

substance shall not be filled or refilled more than six months after the date on which the prescription was issued or be refilled more than five times.

7. A controlled substance shall not be distributed or dispensed other than for a medical purpose.

8. A practitioner, medical group, or pharmacy that is unable to timely comply with the electronic prescribing requirements in subsection 2, paragraph *"b"*, may petition the board for an exemption from the requirements based upon economic hardship, technical limitations that the practitioner, medical group, or pharmacy cannot control, or other exceptional circumstances. The board shall adopt rules establishing the form and specific information to be included in a request for an exemption and the specific criteria to be considered by the board in determining whether to approve a request for an exemption. The board may approve an exemption for a period of time determined by the board not to exceed one year from the date of approval, and may be renewed annually upon request subject to board approval.

Sec. 2. Section 155A.27, Code 2018, is amended by striking the section and inserting in lieu thereof the following:

155A.27 Requirements for prescription.

1. Except when dispensed directly by a prescriber to an ultimate user, a prescription drug shall not be dispensed without a prescription, authorized by a prescriber, and based on a valid patient-prescriber relationship.

2. *a.* Beginning January 1, 2020, every prescription issued for a prescription drug shall be transmitted electronically as an electronic prescription to a pharmacy by a prescriber or the prescriber's authorized agent unless exempt under paragraph *"b"*.

b. Paragraph *"a"* shall not apply to any of the following:

(1) A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

(2) A prescription authorized by a licensed veterinarian.

(3) A prescription for a device.

(4) A prescription dispensed by a department of veterans affairs pharmacy.

(5) A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.

(6) A prescription for a compounded preparation containing two or more components.

(7) A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.

(8) A prescription issued for an opioid antagonist pursuant to section 135.190 or a prescription issued for epinephrine pursuant to section 135.185.

(9) A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy, provided that a prescription issued pursuant to this subparagraph shall indicate on the prescription that the prescriber or pharmacy is experiencing a temporary technical or electronic failure.

(10) A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.

(11) A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board.

c. A practitioner, as defined in section 124.101, subsection 27, paragraph *"a"*, who violates paragraph *"a"* is subject to an administrative penalty of two hundred fifty dollars per violation, up to a maximum of five thousand dollars per calendar year. The assessment of an administrative penalty pursuant to this paragraph by the appropriate licensing board of the practitioner alleged to have violated paragraph *"a"* shall not be considered a disciplinary action and shall not be released or reported as discipline. A practitioner may appeal the assessment of an administrative penalty pursuant to this

paragraph, which shall initiate a contested case proceeding under chapter 17A. A penalty collected pursuant to this paragraph shall be deposited into the drug information program fund established pursuant to section 124.557. The board shall be notified of any administrative penalties assessed by the appropriate professional licensing board and deposited into the drug information program fund under this paragraph.

d. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception under paragraph "*b*" and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription. However, a pharmacist shall exercise professional judgment in identifying and reporting suspected violations of this section to the board or the appropriate professional licensing board of the prescriber.

3. For prescriptions issued prior to January 1, 2020, or for prescriptions exempt from the electronic prescription requirement in subsection 2, paragraph "*b*", a prescriber or the prescriber's authorized agent may transmit a prescription for a prescription drug to a pharmacy by any of the following means:

a. Electronically.

b. By facsimile.

c. Orally.

d. By providing an original signed prescription to a patient or a patient's authorized representative.

4. A prescription shall be issued in compliance with this subsection. Regardless of the means of transmission, a prescriber shall provide verbal verification of a prescription upon request of the pharmacy.

a. If written, electronic, or facsimile, each prescription shall contain all of the following:

(1) The date of issue.

(2) The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.

(3) The name, strength, and quantity of the drug prescribed.

(4) The directions for use of the drug, medicine, or device prescribed.

(5) The name, address, and written or electronic signature of the prescriber issuing the prescription.

(6) The federal drug enforcement administration number, if required under chapter 124.

b. If electronic, each prescription shall comply with all of the following:

(1) The prescriber shall ensure that the electronic system used to transmit the electronic prescription has adequate security and safeguards designed to prevent and detect unauthorized access, modification, or manipulation of the prescription.

(2) Notwithstanding paragraph "*a*", subparagraph (5), for prescriptions that are not controlled substances, if transmitted by an authorized agent, the electronic prescription shall not require the written or electronic signature of the prescriber issuing the prescription.

c. If facsimile, in addition to the requirements of paragraph "*a*", each prescription shall contain all of the following:

(1) The identification number of the facsimile machine which is used to transmit the prescription.

(2) The date and time of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

d. If oral, the prescriber issuing the prescription shall furnish the same information required for a written prescription, except for the written signature and address of the prescriber. Upon receipt of an oral prescription, the recipient shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.

e. A prescription transmitted by electronic, facsimile, or oral means by a prescriber's agent shall also include the name and title of the prescriber's agent completing the transmission.

5. An electronic, facsimile, or oral prescription shall serve as the original signed prescription and the prescriber shall not provide a patient, a patient's authorized representative, or the dispensing pharmacist with a signed written prescription. Prescription records shall be retained pursuant to rules of the board.

6. This section shall not prohibit a pharmacist, in exercising the pharmacist's professional judgment, from dispensing, at one time, additional quantities of a prescription drug, with the exception of a prescription drug that is a controlled substance as defined in section 124.101, up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a ninety-day supply of the prescription drug as specified on the prescription.

7. A prescriber, medical group, institution, or pharmacy that is unable to timely comply with the electronic prescribing requirements in subsection 2, paragraph *"a"*, may petition the board for an exemption from the requirements based upon economic hardship, technical limitations that the prescriber, medical group, institution, or pharmacy cannot control, or other exceptional circumstances. The board shall adopt rules establishing the form and specific information to be included in a request for an exemption and the specific criteria to be considered by the board in determining whether to approve a request for an exemption. The board may approve an exemption for a period of time determined by the board, not to exceed one year from the date of approval, and may be annually renewed subject to board approval upon request.

Sec. 3. Section 155A.29, subsection 4, Code 2018, is amended to read as follows:

4. An authorization to refill a prescription drug order ~~may~~ shall be transmitted to a ~~pharmacist~~ pharmacy by a prescriber or the prescriber's authorized agent ~~through word of mouth, note, telephone, facsimile, or other means of communication initiated by or directed by the practitioner. The transmission shall include the information required~~ pursuant to section 155A.27, except that prescription drug orders for controlled substances shall be transmitted pursuant to section 124.308, and, if not transmitted directly by the practitioner, shall ~~identify by~~ also include the name and title of the practitioner's agent completing the transmission.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the electronic prescribing of prescription drugs, including controlled substances. The bill requires all prescriptions for prescription drugs to transmitted to a pharmacy electronically, effective January 1, 2020. The bill also requires prescriptions for controlled substances that are issued electronically to comply with federal law for the electronic transmittal of prescriptions for controlled substances. The bill provides exemptions from this requirement in certain circumstances and provides alternative methods for the transmittal of prescriptions in those circumstances and for prescriptions transmitted prior to January 1, 2020. The bill also allows a person subject to the requirements of the bill to petition the board of pharmacy for exemption from the requirements of the bill based on economic hardship, technical limitations, or other exceptional circumstances. The bill requires refills for prescription drugs and controlled substances to be transmitted in the same manner as required for initial prescriptions. The bill does not require that a pharmacist who receives a prescription in other than an electronic format to verify that the prescription is subject to an exception. However, the bill directs

pharmacists to use their professional judgment in identifying violations.

A practitioner who does not transmit a prescription drug order electronically as required by the bill shall be subject to an administrative penalty of $250 per violation, up to a maximum of $5,000 per calendar year. Such a penalty shall be assessed by the professional licensing board of the practitioner alleged to have committed the violation. A practitioner may contest such penalty, which shall initiate a contested case proceeding under Code chapter 17A. Any such penalty collected by a professional licensing board shall be deposited into the drug information program fund and reported to the board.

A person who does not comply with Code section 124.308 is guilty of an aggravated misdemeanor pursuant to Code section 124.402. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least $625 but not more than $6,250.